IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: **10/671,519** Confirmation No.: **9109**
Applicant: **Takafumi KUROSAWA** Art Unit: **1614**
Filed: **September 29, 2003** Examiner: **Jones, Dwayne C.**
Docket No: **SHD-103-USAP** Customer No: **28892**
For: **External Skin Preparation**

TRANSMITTAL

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Sir:

Transmitted herewith is Applicants' Appeal Brief together with the requisite filing fee in the amount of $500.00. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account 19-2816. A duplicate copy of this Transmittal is attached.

Respectfully submitted,

Ronald R. Snider
Reg. No. 24,962

Date: October 4, 2006

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APPEAL BRIEF

Applicant hereby submits its Appeal Brief pursuant to 37 CFR §1.192.

Ronald R. Snider
Registration No. 24,962

Date: October 4, 2006

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(C) REAL PARTY IN INTEREST

Shiseido Company, Ltd.

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Tokyo JAPAN 104-8010

(D) RELATED APPEALS AND INTERFERENCES

None

(E) STATUS OF CLAIMS

Claims 1 -7 are pending in the application and have been rejected in the final Office Action dated February 6, 2006. All claims are rejected under 35 USC 103(a) as being unpatentable over Lentini et al. of WO 00/33803 in view of Katsuhiro of JP 01165517.

Claim 1: Rejected, On Appeal

Claim 2: Rejected, On Appeal

Claim 3: Rejected, On Appeal

Claim 4: Rejected, On Appeal

Claim 5: Rejected, On Appeal

Claim 6: Rejected, On Appeal

Claim 7: Rejected, On Appeal

(F) STATUS OF AMENDMENTS

An amendment dated July 5, 2006 was filed after the Final Office Action which is dated February 6, 2006. The amendment dated July 5, 2006 was entered by the Advisory Action dated July 20, 2006.

In this amendment, the spelling of the word perfluoroalkylphosphate was corrected in claims 1, 3, and 4.

(G) SUMMARY OF CLAIMED SUBJECT MATTER

Applicant's invention is best understood by consideration of the claims and their application to the drawings. The claims are as follows:

Claim 1

Claim 1 is for an external skin preparation comprising (1) octyl methoxycinnamate and other constituents. The octyl methoxycinnamate is a known ultraviolet absorbent used in sun screens. Titanium oxide, or zinc oxide when mixed with octyl methoxycinnamate causes skin irritation (page 2, line 15).

In clause 1, Applicant claims octyl methoxycinnamate.

In clause 3, Applicant claims selection from the group consisting of polyoxyethylene methyl glucoside (disclosed at page 2, lines 20 - 21) and polyoxypropylene methyl glucoside (disclosed at page 2, line 21. Applicant teaches that these glucosides can be used to reduce skin irritation.

In clause 2, Applicant claims the oxides selected from the group consisting of titanium oxide, zinc oxide and mixtures thereof. As pointed out above, however, these oxides may cause skin irritation when used with octyl methoxycinnamate.

Applicant teaches that it is known to use zinc oxide together with octyl methoxycinnamate (page 4, lines 16 - 19) for sunscreens. Applicant teaches that it is the co-presence of octyl

methoxycinnamate and the titanium or zinc oxide that triggers the irritation (page 11, lines 3 - 4).

Clause 2 further says:

> "wherein the said oxides are treated in a hydrophobic manner selected from the group consisting of methyl hydrogen polysiloxane (see Table 1, Example 5) and silane coupling agents, metal soap processing, fluorine processing with perfluoroalkylphosphate diethanolamine salt and perfluoroalkylsilane and processing with dextrin fatty acid ester". (Claim 1, lines 4 - 11)

This Markush group is set forth at page 5, lines 8 -14. The purpose of the Markush group claimed substances to treat the titanium oxide or zinc oxide powders in order to further reduce the irritant effect of the oxides when used with octyl methoxycinnamate.

In claim 1, there are two compositions which reduce the irritant effect. These are the use of the glucoside (clause 3) and the hydrophobic treatment of the titanium or zinc oxide by use of the materials set forth in the Markush group identified at page 5, lines 8 - 14 and which is set forth in claim 1, beginning at line 6 (clause 2).

Claim 3

Claim 3 in its preamble claims an agent for reducing skin irritation of octyl methoxycinnamate. Claim 3, therefore, differs from claim 1 only in the preamble. In claim 3, Applicant specifies the problem in the preamble which is the irritation caused by octyl methoxycinnamate as set forth in Applicant's specification, page 2, line 15.

The body of claim 3 is the same as the body of claim 1.

Claim 4

Claim 4 differs from claims 1 and 3 in that claim 4 is directed to a method of reducing skin irritation of octyl methoxycinnamate as opposed to a composition claim.

The body of claim 4 is identical to the body of claims 3 and 1.

(H) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. The rejection of claims 1 - 7 under 35 USC § 103(a) as being unpatentable over Lentini et al. WO 00/33803 in view of Katsuhiro JP 01165517 on the grounds that it is *prima facie* obvious to combine two compositions citing *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See Final Office Action, pages 5 - 7, paragraphs 9 - 12 and response to arguments, pages 2 - 4, paragraphs 4 - 7.

2. The rejection of claims 1 - 7 under 35 USC § 103(a) as being unpatentable over Lentini et al. WO 00/33803 in view of Katsuhiro JP '517 when the amended claims included a new Markush group (column 1, lines 4 - 7) which is not disclosed in the art. See Final Office Action at page 4, paragraph 8. The Examiner realized that the initial Office Action did not address the issues of patentability raised by the amendment to include the Markush group (claim 1, lines 4 - 11).

(I) ARGUMENT

1. Specific Limitation Not Described

Under the previous rules (37 CFR § 1.192(C)(a)(iv), for each rejection under 35 USC § 103, the Applicant's argument was required to specify the errors in the rejection and, if appropriate, specific limitations in the rejected claims which are not described in the prior art relied upon in the rejection. Applicant was further required to explain how such limitations render the claimed subject matter unobvious. Here, the specific limitation not described in the prior art is the Markush group (claims 1, lines 4 - 11). The Examiner argued that Lentini includes a fluoropolymer then reasoned that all fluoropolymers are suggested. This cannot be construed to be a necessary teaching or suggestion of the specific claimed members of the Markush group.

2. The References

a. Lentini US Patent 6,294,156 (WO 00/33803)

Lentini WO 00/33803 is the same specification as US Patent 6,294,156. Citations to both patents are provided in this argument. US Patent 6,294,156 is a 1449 submission.

Lentini is for a composition with enhanced photo protective effect which relies upon the use of a fluororesin having a submicron size in combination with a sunscreen agent and oil component (Title and Abstract, US column 2, lines 49 - 51; WO '803

front page, page 3, lines 10 - 12). Lentini further provides for boosting of SPF (skin protection factor) value by reducing irritation caused by irritating sunscreen agents. (Abstract, US column 2, lines 10 - 15; WO '803 front page, page 2, lines 16 - 19). Lentini reduces irritation because the enhanced photo protection is not achieved by use of more sunscreen agent (US column 1, lines 13 - 17; WO '803 page 1, lines 8 - 10). Lentini reduces the sunscreen agent to reduce irritation. Lentini teaches that zinc oxide and titanium dioxide are inorganic sunscreen agents (US column 1, line 47 - 53, Column 4, line 17; WO '803 page 1, lines 31 to page 2 line 2, page 5, line 11). Throughout Lentini it is stated that it is an objective to increase the SPF and reduce irritation by reducing the sunscreen compositions to accepted levels (US, column 2, lines 8 - 14, column 2, lines 26 - 27, column 4, line 64 to column 5, line 5; WO '803 page 2, lines 15 - 19, lines 27 - 28, page 6, lines 8 - 12). An objective is to reduce the amount of zinc oxide or titanium dioxide if present (column 5, lines 1 - 3; WO '803 page 6, lines 9 - 11).

Lentini uses fluororesin polymers in a hydrophobic vehicle to reduce the presence of other irritating materials (US column 2, lines 18 - 21, column 3, lines 35 - 59; WO '803 page 2, lines 22 - 24, page 4, lines 12 - 27). Therefore, no increase in sunscreen agents is required to get an increased SPF (US column 2, lines 26 - 32; WO '803 page 2, lines 27 - 31). Lentini teaches use of octyl methoxycinnamate, without a larger quantity of inorganic or organic sunscreen agents (US column 2, lines 35 - 44; WO '803 page 3, lines

1 - 7). Lentini describes his fluororesin (PTFE or polytetrafluorethylene) as a dry powder (US column 3, lines 19 - 27; WO '803 page 4, lines 3 - 7). The fluororesin of Lentini is incorporated into "oil" in order to become hydrophobic (US column 3, lines 35 - 38; WO '803 page 4, lines 12 - 14). The fluororesin is clearly not hydrophobic until treated. The hydrophobic material can be a carbon oil (US column 3, lines 60 - 63; WO '803, page 4, lines 28 - 30).

Lentini teaches that the fluororesin (PTFE) can enhance the octyl methoxycinnamate sun screening agent (US column 4, line 12, US column 4, line 35; WO '803 page 5, line 22). The fluororesin (PTFE) is also used to enhance zinc oxide and titanium dioxide (US column 4, line 17; WO '803 page 5, line 11) or mixtures of various sun screening agents (US column 4, line 33; WO '803 page 5, line 20). The addition of PTFE can reduce the amount of TO_2 from 8 - 12% to 1 - 2% for the same SPF (column 4, lines 50 - 63; WO '803 page 5, line 31 to page 6, line 6).

Lentini teaches that the addition of the fluororesin with the sunscreens reduces the irritation caused by the sunscreens, such as titanium dioxide, octyl methoxycinnamate, (US column 4, line 64 to column 5, line 5; WO '803 page 6, lines 7 - 12). Lentini teaches that the inorganic sunscreens can be completely eliminated (US column 5, line 42; WO '803 page 7, line 2). Lentini's Examples 1 and 2 are with and without 2.8 percent fluororesin. The examples show that the fluororesin containing sunscreen is better than where

the sunscreen is only an octyl methoxycinnamate based material. The examples do not include oxides at all.

The fluororesin of Lentini is only teflon, and not all fluoropolymers or all fluororesin polymers.

The Lentini reference (US case) incorporates by reference US patents 5,093,110 and 4,052,278 to illustrate Teflon particles. These incorporations show that the PTFE is a fluororesin and not any fluorinated polymer.

b. Katsuhiro JP 01165517

Katsuhiro only teaches use of titanium dioxide along with polyoxethylene methylglycoside. This reference includes none of the compositions of Applicant's Markush group of clause 2 (Claim 1, lines 4 - 11). A copy of this reference is included in the Evidence Appendix (K).

3. First Ground of Rejection

a. The Rejection

In the Final Office Action dated February 6, 2006, beginning at page 5, paragraphs 9 - 12, the Examiner stated his reasons for his rejection of the claims under 35 USC § 103. This statement is a verbatim repeat of the initial July 6, 2005 Office Action rejection, which was directed to different claims than those on appeal. The initial office action was directed to claim 1 as originally filed, which did not include the Markush group (claim 1,

lines 4 - 11) found in clause 2 of each of the appealed independent claims.

b. *In re Kerkhoven* 626 F.2d 846, 205 USPQ 1069 (CCPA 1980)

The Examiner relies upon the often quoted *Kerkhoven* decision which states in part as follows:

> "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition that is to be used for the very same purpose." (page 1072)

Kerkhoven does not apply to any of the claims on appeal. Initially, Applicant claimed only (1) octyl methoxycinnamate, (2) an oxide selected from the group consisting of titanium oxide, zinc oxide and mixtures thereof, and (3) glucoside selected from the group consisting of polyoxyethylene methyl glucoside, polyoxypropylene methyl glucoside and mixture thereof (Applicant's originally filed claim 1). This claim was rejected on the basis of *Kerkhoven*. In response, Applicant amended claim 1 on December 27, 2005 to include the additional Markush limitation:

> ". . . wherein the said oxides are treated in a hydrophobic manner selected from the group consisting of methyl hydrogen polysiloxane and silane coupling agents, metal soap processing, fluorine processing with perfluoroalkylphosphate diethanolamine salt and perfluoroalkylsilane and processing with dextrin fatty acid ester . . ." (claim 1, lines 4 - 11)

Kerkhoven requires a mixture of two compositions, each of which is taught by the prior art to be useful for the same purpose. The prior art here teaches only octyl methoxycinnamate combined

with titanium oxide and zinc oxide and the use of titanium oxide and zinc oxide combined with glucosides (JP '517). The items enumerated in the Markush group limitation (claim 1, lines 4 - 11) are not present in these two references.

The combination of the two references does not make out a *prima facie* case. The claimed invention is not simply mixing known compositions because the claimed compositions (Markush group, claim 1, lines 4 - 11) are not taught by the prior art of record. Kerkhoven is inapplicable to these claims.

4. Second Ground of Rejection

a. Applicant's Compounds are not Previously Known to the Art of Record

The Examiner in his comments included with the Advisory Action states that "the instant claims are composition claims of previously known compounds." Applicant respectfully submits that the cited prior art does not include oxides of titanium or zinc treated in the hydrophobic manner set forth in the compositions of Markush group (claim 1, lines 4 - 7). The Examiner has not included any evidence that the constituents of this Markush group were previously known in the references.

b. Page 4, Paragraph 8 Final Office Action

In the Final Office Action at page 4, paragraph number 8, the Examiner first addressed the newly presented claims, which included the Markush group from lines 4 - 11 of claim 1. At page 5, line 7

the Examiner argues that there is an explicit teaching of "combining or treating any fluorinated polymer with a hydrophobic manner".

Applicant has performed word searches and identified terms not found in the Lentini reference, or in the secondary reference:

> An external skin preparation comprising:
> (1) octyl methoxycinnamate,
> (2) oxide selected from the group consisting of titanium oxide, zinc oxide and mixtures thereof, wherein the said oxides are treated in a hydrophobic manner selected from the group consisting of methyl hydrogen polysiloxane and silane coupling agents, metal soap processing, fluorine processing with perfluoroalkylphosphate diethanolamine salt and perfluoroalkylsilane and processing with dextrin fatty acid ester, and
> (3) glucoside selected from the group consisting of polyoxyethylene methyl glucoside, polyoxypropylene methyl glucoside and mixture thereof.

In the above quoted portion of the claim, none of the underlined claim terms appear in the Lentini or the Katsuhiro references. Therefore, this appeal turns on whether the Examiner is correct in arguing that there is a teaching of combining or treating TiO or ZnO with any fluorinated polymer with a hydrophobic manner and that this suggests Applicant's hydrophobic treatment of TiO_2 or ZnO with the Markush group from Lines 4 - 11 of Claim 1.

Lentini discloses a fluorinated polymer, but it is teflon powder. Lentini does not suggest that his fluorinated polymer (PTFE) teflon is generic to all fluorinated polymers. Lentini does not teach that his fluorinated polymer (PTFE) is used to treat ZnO or TiO_2 in a hydrophobic manner.

Lentini discloses that the SPF value of the sunscreen composition can be increased, but that it is with the fluororesin

polymer, and not the substances set forth in the Markush group (claim 1, lines 4 - 11). The Examiner asserts that "fluororesins can be any polymer" (page four, line 21); that the fluororesin is incorporated in an oil component (page 4, line 22).

The Examiner erroneously argues that these Lentini teachings guide the artisan to use "any fluorinated polymer" along with a known sunscreen agent in order to increase SPF of the sunscreen composition. In fact, Lentini teaches only the use of fluorinated resins and specifically teaches the use of teflon. Applicant respectfully submits that the Examiner's argument does not make a *prima facie* case of obviousness. All fluorine compounds or all fluorine polymers are not rendered obvious by the presence of a single fluororesin (teflon) in Lentini.

Applicant does not claim any fluorinated polymer. Applicant claims the Markush group, that is specific compounds which are clearly not suggested by the art of record.

In the claims, the oxides of titanium oxide and zinc oxide are treated in a hydrophobic manner with the treatments specified in the Markush group (claim 1, lines 4 - 11). Applicant does not claim and never claimed treatment of a fluorinated polymer. Applicant uses entirely different chemistry, namely fluorine processing with perfluoroalkylphosphate diethanolamine salt and perfluoroalkylsilane. These two substances are clearly not PTFE or Teflon.

The Examiner cites page 3, lines 10 - 12 of WO 00/33803. The Examiner argues that Applicant admits that Lentini teaches of the

presence of a fluorinated polymer that is incorporated into sunscreen composition. Applicant agrees only that Lentini teaches the use of Teflon (PTFE), which is a fluorinated fluororesin having a network structure. On the other hand, fluorinated polymers have no network structure like a resin has. Lentini does not teach or suggest the claimed fluorinated polymers set forth in the Markush group.

c. Fluororesin Particle Size and Friction Properties are not Relevant

The submicron particle size referred to is that of the Teflon fluororesin, and is not in any way related to the fluoro material set forth in the Markush group (claim 1, lines 4 - 11). The PTFE particles are not suggested to be substances which can be used to coat the zinc or titanium dioxide to provide the claimed treatment in a hydrophobic manner.

The Examiner cites page 4, line 3, of Lentini which reads as follows:

> The fluororesin can be any fluorinated polymer that is well known for having low friction properties and for being used as a dry lubricant powder.

The Examiner read a portion of the sentence out of context and eliminated friction properties and being used for a dry lubricant powder. Still further, the Examiner ignores that the fluororesin is preferably PTFE, commonly known as Teflon (see next sentence). This is not the claimed hydrophobic manner

fluorine processing with perfluoroalkylphosphate or perfluoroalkylsilane.

d. Fluororesin in Oil is not Claimed or Relevant

The Examiner cites page 4, line 12 of WO 00/33803 (US column 3, line 35) that in its entirety reads as follows:

> The fluororesin is incorporated into an oil component of the final composition. The oil component can be any cosmetically or pharmaceutically acceptable vehicle that is hydrophobic (i.e., oil based).

This is only a teaching of incorporation of the fluororesin with an oil-based material. It is not, however a teaching of or suggestion of incorporation of zinc oxide or titanium oxide into the claimed materials in Applicant's Markush group (claim 1, lines 4 - 11). Lentini teaches only that PTFE used as a dry lubricant powder (see page 4, line 4), may be used with oil-based materials.

The Examiner refers to oil components, however, oil components do not by themselves suggest the specific claimed components set forth in Applicant's claims. It is well known that oil components are known in every field of endeavor. However, specific components such as those claimed by Applicant cannot be suggested or made obvious by this common knowledge of oils.

The Examiner states at page 4, line 28, "Alternatively, the fluororesin can be pre-dispersed in a hydrocarbon oil and, preferably, in polyisobutene." This is not claimed.

The fluororesin can be predispersed in a hydrocarbon oil (page 5, line 1). But this is not relevant to Applicant's claim of treating TiO_2 or ZnO in a hydrophobic manner from the group of compounds stated in the Markush group (claim 1, lines 4 - 11).

The Examiner argues at page 5 that Lentini states that the fluorinated polymer is incorporated or treated with an oil, a hydrocarbon oil, or even a vehicle that is hydrophobic. The Examiner then goes on to argue that this would suggest to those skilled in the art to combine any fluorinated polymer in a hydrophobic manner.

The Examiner contends that this is a teaching of and guide to one of skill in the art to use <u>any fluorinated polymer</u> along with any known sunscreen agent in order to increase the SPF of the sunscreen composition. This is, however, not the gist of what is claimed in the Markush group. <u>The Examiner has not addressed the terms of the Markush group, or in any way shown how the terms of the Markush group can be rendered obvious by teachings of hydrocarbon oils which are not claimed</u>.

<u>e. The Genus does not Legally Suggest or Teach the Species</u>

<u>1. The Federal Circuit</u>

The Examiner's rejection is premised upon the reported identification of a fluorinated polymer in Lentini coupled with an unstated argument that such a fluorinated polymer would make all fluorinated polymers obvious. This boils down to an argument that the disclosure of a genus suggests and makes obvious any

possible species. Here, the genius of fluoropolymers cannot be used to suggest the species set forth in the Markush group (claim 1, lines 4 - 11). As stated in *In re Baird*, 16 F.3d 380, 229 USPQ2d 1550 (Fed. Cir. 1994), the fact that a claimed compound may be encompassed by a disclosed generic formula does not itself render that compound obvious. Here, the Examiner has shown nothing in Lentini which would suggest to one of ordinary skill in the art use of Applicant's claimed compounds. Such a suggestion might take the form of a preference or other teaching or pointing in the direction of Applicant's compounds. The Examiner has pointed to none. There are no preferences in Lentini. See also *In re Jones*, 958 F.2d 347, 350 221 USPQ2d 1941, 1943 (Fed. Cir. 1992).

2. Board of Appeals Decisions

The principle for which In re Baird and In re Jones stands has often been affirmed by the Board of Patent Appeals and Interferences in decisions which are now available to the public at the Patent Office web site. Although these decisions are not binding precedent, and not written for publication, they are now published and searchable through search engines such as Google. Applicant brings to the attention of the Board *Ex parte Dorschaub* et al. Appeal No. 2001-1586, application number 08/402,394. In this decision, the Board considered whether the Examiner had shown any motivation which would support a conclusion of non-obviousness. The Board concluded there was none. Similarly, in

this case the Examiner has shown no motivation at all which would lead one to suggest the fluorocompounds in Applicant's Markush group of claim 1, lines 4 - 11. In *Ex parte Lemann*, Appeal No. 2006-0391, Application No. 10/366,371, heard March 7, 2006, the Board similarly reversed an Examiner where the rejection was mere picking and choosing amongst a genus of compounds. Reliance was placed upon *In re Baird., supra*. The Board required the Examiner to show some suggestion or motivation to make the claimed species or subgenus in order to render the claimed invention obvious. Here the Examiner has shown no motivation or suggestion. In *Ex parte Anderson*, Appeal No. 1998-2622, the Board again, on the basis of *In re Baird*, and *In re Jones* required that there be a showing of a suggestion or motivation to modify the teachings of the reference to the claimed subject matter in order to reach an obviousness conclusion. In *Ex parte Brahm et al.*, Appeal No 1997-3039, Application No. 08/436,939, the Board again determined on the basis of In re Baird the fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.

The principles of these Board decisions compel reversal in this case because there is no teaching or suggestion of the fluorocompounds of the Markush group. Here, the claimed compound sets forth in the Markush group have not even been shown to be species of the teflon resin in the Lentini reference.

The above four Board decisions are included with the Appendix M which is entitled "Non-Binding Precedent of the

Board." Although non-binding, comity and deference are appropriate.

3. A *Prima Facie* Case is Initially Required

The Board of Appeals has reaffirmed its guidance from the Federal Circuit by stating:

> "It is well established that the examiner has the initial burden under § 103 to establish a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 14455, 24 USPQ2d 1443, (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). To that end, it is the examiner's responsibility to show that some objective teaching or suggestion in the applied prior art, or knowledge generally available [in the art] would have led one of ordinary skill in the art to combine the references to arrive at the claimed invention. *Pro-Mold & Tool Co., v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996)." (*Ex parte Lemann, supra*)

MPEP § 2142. confirms this requirement, but in less succinct language.

MPEP § 2144.08 II A 4 (a - f) outlines consideration for determination of the question of whether a *prima facie* case of obviousness exists in the case of genus and species. The considerations are:

(a) consider the size of the genus,

(b) consider the expressed teachings,

(c) consider the teaching of structural similarity,

(d) consider the teachings of similar properties or uses,

(e) consider the predictability of the technology,

(f) consider any other teachings to support selection of a species or subgenus.

4. The Examiner did not State a *Prima Facie* Case

In the Examiner's argument in the Final Office Action, page 4, none of the MPEP § 2144.08 II A 4 analysis is followed. The MPEP § 2144.08 at page 2100-162 also provides a step-by-step diagram of analysis utilizing the above factors. The Examiner's analysis never stated the size of the genus, never pointed to any expressed teaching that would have motivated the selection, never discussed structural similarity between teflon the and claimed compounds, never showed that there were teachings of similar properties or uses and never showed that the art was predictable such that similar properties would be expected (no showing that teflon is similar to compounds in the Markush group (claim 1, lines 4 - 11). Based upon the MPEP guideline, the claim clearly should have been considered non-obvious under § 103.

5. Conclusion

The Examiner's rejection must be reversed.

Respectfully submitted,

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(J) CLAIMS APPENDIX

1. (currently amended) An external skin preparation comprising:

(1) octyl methoxycinnamate,

(2) oxide selected from the group consisting of titanium oxide, zinc oxide and mixtures thereof, wherein the said oxides are treated in a hydrophobic manner selected from the group consisting of methyl hydrogen polysiloxane and silane coupling agents, metal soap processing, fluorine processing with perfluoroalkylphosphate diethanolamine salt and perfluoroalkylsilane and processing with dextrin fatty acid ester, and

(3) glucoside selected from the group consisting of polyoxyethylene methyl glucoside, polyoxypropylene methyl glucoside and mixture thereof.

2. (original) An external skin preparation according to claim 1, which is a sun-screening cosmetic.

3. (currently amended) An agent for reducing the skin irritation of octyl methoxycinnamate in an external skin preparation comprising:

(1) octyl methoxycinnamate,

(2) oxide selected from the group consisting of titanium oxide, zinc oxide and mixtures thereof, wherein the oxides are treated in a hydrophobic manner selected from the group consisting of methyl hydrogen polysiloxane and silane coupling agents, metal soap processing, fluorine processing with perfluoroalkylphosphate diethanolamine salt and perfluoroalkylsilane and processing with dextrin fatty acid ester, and

(3) glucoside selected from the group consisting of polyoxyethylene methyl glucoside, polyoxypropylene methyl glucoside and mixture thereof.

4. (currently amended) A method of reducing the skin irritation of octyl methoxycinnamate in an external skin preparation comprising:

(1) octyl methoxycinnamate,

(2) oxide selected from the group consisting of titanium oxide, zinc oxide and mixtures thereof, wherein the oxides are treated in a hydrophobic manner selected from the group consisting of methyl hydrogen polysiloxane and silane coupling agents, metal soap processing, fluorine processing with perfluoroalkylphosphate diethanolamine salt and perfluoroalkylsilane and processing with dextrin fatty acid ester, and

(3) glucoside selected from the group consisting of polyoxyethylene methyl glucoside, polyoxypropylene methyl glucoside and mixture thereof.

5. (previously presented) An external preparation according to claim 1, wherein the octyl methoxycinnamate is at least 10% by weight.

6. (previously presented) An external preparation according to claim 1, wherein the octyl methoxycinnamate is in the range of 1.0 to 15% by weight.

7. (previously presented) An external preparation according to claim 6, wherein the octyl methoxycinnamate is in the range of 2.0 to 10% by weight.

(K) EVIDENCE APPENDIX

The references listed below were 1449 submissions considered by the Examiner and entered into the record in the Office Action of July 6, 2005.

Nakaoka Katsuhiro	JP 01165517	June 29, 1989
Peter J. Lentini et al.	WO 00/33803	June 15, 2000
Peter J. Lentini et al.	US 6,294,156	September 29, 2001

(L) RELATED PROCEEDINGS APPENDIX

None

(M) NON-BINDING PRECEDENT OF THE BOARD

Ex parte Martin Brahm, Eberhard Arning, Lutz Schmalstieg, Harald Mertes and Jurgen Schwindt, Appeal No. 1997-3039, Application No. 08/436,939

Ex parte Richard L. Anderson and Bruce B. Randolph, Appeal No. 1998-2622, Application No. 08/530,684

Ex parte Michael Dorschub, Paul Habermann, Gerhard Seipke and Eugen Uhlmann, Appeal No. 2001-1586, Application No. 08/402,394

Ex parte Patricia Lemann, Annick Collette and Isabelle Bara, Appeal No. 2006-0391, Application No. 10/366,371, Heard March 7, 2006

EUROPEAN PATENT FFICE

Patent Abstracts of Japan

PUBLICATION NUMBER : 01165517
PUBLICATION DATE : 29-06-89

APPLICATION DATE : 23-12-87
APPLICATION NUMBER : 62326401

APPLICANT : ION KAGAKU KK;

INVENTOR : NAKAOKA KATSUHIRO;

INT.CL. : A61K 7/42

TITLE : DERMAL COSMETIC FOR PROTECTING SKIN FROM ULTRAVIOLET RAYS AND PRODUCTION THEREOF

ABSTRACT : PURPOSE: To obtain the title cosmetic, containing ultrafine titanium dioxide particles, capable of sustaining effects on prevention of ultraviolet rays, further transparent when applied to the skin without damaging the skin and freely applicable to any part of the body.

CONSTITUTION: A cosmetic containing (A) 5~25wt.% 10% aqueous solution of ultrafine titanium dioxide particles having 100~200nm particle diameter, (B) 3~10wt.% polyoxyethylene methylglycoside (10~20 EO), (C) 1~3wt.% polyoxyethylene (7mol monofatty acid glyceryl and (E) 42~86wt.% purified water. The above-mentioned cosmetic is prepared by adding the ingredient (D) to the ingredient (A), blending both at ambient temperature, adding the ingredients (C), (B) and (E) in the order mentioned to the resultant blend solution while blending the ingredients each time. Alternatively, a prescribed amount of the afore-mentioned stock solution of the cosmetic is separated and collected in a pressure-resistant container, which is then hermetically sealed. Deodorized liquefied petroleum gas or fluorocarbon gas is then injected to provide a simply usable aerosol cosmetic.

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International Bureau

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(54) Title: COMPOSITIONS WITH ENHANCED PHOTOPROTECTIVE EFFECT AND METHOD FOR USING SAME

(57) Abstract

The present invention relates to a sunscreen composition for topical application to the skin comprising a fluororesin having a submicron in combination with a sunscreen agent and an oil component. These compositions provide a boost in the SPF value of the composition. The invention also provides methods relating to the use of these compositions for boosting the SPF and decreasing the irritation on the skin caused by irritating sunscreen agents.

COMPOSITIONS WITH ENHANCED PHOTOPROTECTIVE EFFECT AND METHOD FOR USING SAME

Field of the Invention

The present invention relates to topically applied sunscreen compositions. In particular, the invention relates to sunscreen compositions containing sunscreen agents that provide an enhanced amount of photoprotection by means of being in combination with submicron fluororesin particles. The sunscreen compositions feel better on the skin and are less irritating than typical sunscreens because the enhanced photoprotection is not achieved by using greater quantities of the sunscreen agent.

Background of the Invention

Sunscreen compositions are frequently used to protect skin that is exposed to the sun for a variety of reasons such as sun bathing, or spending leisure time or working out of doors. Topical sunscreen compositions, which are easily applied to the skin, are usually in the form of a lotion, oil, cream or emulsion (water-in-oil and oil-in-water). Sunscreen compositions contain sunscreen agents to protect the skin from the harmful UV rays of the sun. These rays are generally in the form of UV-A and UV-B radiation which range from about 290 to 400 nm in wavelength.

There are short and long term hazards associated with prolonged exposure to UV radiation. Some of the long term effects include malignant changes in the skin surface, premature aging of the skin as evidenced by wrinkles, yellowing, cracking, telangiectasis (spider vessels), solar keratoses (growths), ecchymoses (subcutaneous hemorrhagic lesions), and loss of elasticity (sagging). A major short term effect of prolonged exposure to UV light is erythema, commonly known as a sunburn.

The amount of photoprotection against erythema is the basis for the determination of the SPF ("sun protection factor") value. The SPF value measures the amount of protection from the sun provided before a certain level of erythema is experienced. Compositions having higher SPF values are preferred because they offer more protection against the harmful effects caused by the sun and UV radiation.

Sunscreen agents act by absorbing, scattering or blocking UV radiation and thus, prevent UV radiation from penetrating the skin. They are available as both organic and inorganic agents. Typical organic agents include, for example, PABAs (p-aminobenzoic acids), benzophenones,

salicylate esters and dioxybenzone. Examples of inorganic agents include zinc oxide, titanium dioxide and calamine. To achieve higher SPF values, typically, greater quantities of the sunscreen agent or combination of sunscreen agents are added to the composition. However, greater quantities of sunscreen agents present certain challenges in formulation, especially with respect to stability. For example, titanium dioxide tends to agglomerate and become less effective as a sunscreen agent. It is also a frequent complaint that sunscreens containing particularly high concentrations of titanium dioxide have an unpleasant or grimy feel on the skin and result in a white or blue hue on the skin. Other negative qualities that result from using high concentrations of inorganic sunscreen agents are the opaqueness of the formula when a clear formula is desired. the change in color of the formula, or other adverse aesthetic effects.

Producing a topical sunscreen composition with a high SPF is difficult to achieve without the negative characteristics associated with using larger quantities of sunscreen agents. Efforts to "boost" the SPF value of a sunscreen composition are demonstrated in U.S. Patent Nos. 5,468,471 and 5,573,754. However, they include components in addition to the sunscreen agent that are relatively costly and not easily manufactured. Thus, there is a continued effort to find ways of boosting the SPF of topical sunscreen compositions. It is, therefore, an object of the present invention to reduce the irritation potential of topical sunscreen compositions to levels which will be acceptable to the average user of the product and to provide a topical sunscreen composition that is appealing to the consumer.

Summary of the Invention

The present invention relates to a sunscreen composition that has a photoprotective effect enhanced by the combination of a fluororesin polymer of a submicron particle size and a sunscreen agent in a hydrophobic vehicle. The composition enhances the photoprotective effect of the composition without causing adverse skin reactions or being aesthetically unpleasant to the user. An enhancement of the photoprotective effect can be demonstrated, for example, by an increase in SPF by 2 or 3 units. The increase is achieved primarily without adding larger quantities of the sunscreen agent. The invention also relates to a cosmetic or pharmaceutical composition comprising the combination, as well as a method of boosting the SPF value of a sunscreen and methods for reducing the irritancy experienced on the skin and providing photoprotection to the skin by applying to the skin the compositions of the present invention.

The invention is particularly useful in the preparation of formulations containing octyl methoxycinnamate and benzophenone as well as other organic sunscreen agents because the SPF is increased without adding larger quantities of these organic sunscreen agents or other inorganic sunscreens. Therefore, the stability and aesthetic challenges experienced with larger quantities of organic and inorganic sunscreen agents can be avoided. The compositions and methods of the present invention feel comfortable on the skin, look more appealing and achieve an increased SPF value.

Detailed Description of the Invention

It has now been unexpectedly discovered that the SPF value of a sunscreen composition can be increased when a fluororesin polymer having a submicron particle size is combined with a sunscreen agent. The fluororesin polymer of the present invention has been previously used in cosmetic products as described in Japanese Publication Nos. 06-135820, 05-163114, 02-088512, and U.S. Patent No. 5,093,110, the contents of which are herein incorporated by reference. Fluororesins have been previously described for use in sunscreen compositions, as for example, in Japanese Application Disclosure Nos. 60-149515, 05-339139. However, the use of fluororesins in sunscreens has been in an arrangement where the sunscreen agent surrounds the fluororesin (i.e., the fluororesin is "coated" by the sunscreen) or is bonded to the fluororesin by a chemical reaction. In the present invention the advantages of combining the sunscreen agent with the submicron fluororesin in a composition are described and found to surprisingly boost SPF and reduce irritation on the skin. These benefits and characteristics have not previously been disclosed.

It has been discovered that a certain particle size range of known fluororesins are capable of enhancing the SPF of sunscreen agents. The submicron size of the fluororesin particles effects the ability of fluororesin to achieve, when combined with the sunscreen agent, a boost in the SPF value of the sunscreen composition. The particle size ranges from about 200 nm to about 1200 nm, preferably between about 400 to about 800 nm, and more preferably about 600 nm. The fluororesin can be made by any method known in the art. Methodology for production of submicron fluororesin, for example, is disclosed in U.S. Pat. No. 4,052,278, the contents of which are incorporated herein by reference. While not wishing to be bound by any particular theory, it is believed that the efficacy of these sunscreen compositions in substantially increasing the SPF value of the composition is related to the optical properties of the submicron sized

fluororesin particles, which synergistically along with the sunscreen agent prevent the harmful rays of the sun from damaging the skin.

The fluororesins can be any fluorinated polymer which is well known for having low friction properties and for being used as a dry lubricant powder. Preferably, the fluororesin is polytetrafluorethylene ("PTFE"), commonly known as Teflon and available from E.I. Du Pont de Nemours and Company. The fluororesin is a polymer and has a degree of polymerization greater than 20,000. In particular, PTFE is non-sticky and very inert chemically. Therefore, the submicron PTFE particles of the present invention do not react with the other components of the sunscreen composition, but rather, synergistically coexist with the other components. The PTFE is present in the composition in an amount of about 0.1 to about 10.0 percent of the weight of the composition, preferably 0.2 to about 5.0 percent, and more preferably about 0.5 to about 1.0.

The fluororesin is incorporated into an oil component of the final composition. The oil component can be any cosmetically or pharmaceutically acceptable vehicle that is hydrophobic (i.e., oil based). The oil component of the present composition can, in general, include other types of materials that are cosmetically or pharmaceutically acceptable and which are substantially insoluble in water. The materials may be, for example, organic esters or volatile or non-volatile oils. For example, suitable volatile oils include, but are not limited to, both cyclic and linear silicones, such as cyclomethicone, octamethylcyclotetrasiloxane, and decamethylcyclopentasiloxane, or a mixture thereof. Non-volatile oils include, but are not limited to, vegetable oils, such as coconut oil, jojoba oil, corn oil, sunflower oil, palm oil, soybean oil; non-volatile silicones, such as dimethicone, dimethiconol, dimethicone copolyol, phenyl trimethicone, methicone, simethicone; organic esters such as carboxylic acid esters and glyceryl esters. For example, carboxylic acid esters can include isostearyl neopentanoate, cetyl octanoate, cetyl ricinoleate, octyl palmitate, dioctyl malate, coco-dicaprylate/caprate, decyl isostearate, myristyl myristate; animal oils such as lanolin and lanolin derivatives, tallow, mink oil or cholesterol; and glyceryl esters can include glyceryl stearate, glyceryl dioleate, glyceryl distearate, glyceryl linoleate, glyceryl myristate.

Alternatively, the fluororesin can be pre-dispersed in a hydrocarbon oil and, preferably, in polyisobutene. The hydrocarbon oil may be any hydrocarbon that exists as a liquid at room temperature and has a relatively low viscosity. Therefore, the hydrocarbon oil may be volatile or non-volatile, or a mixture of both. Examples include, but are not limited to, straight or branched chain hydrocarbons having from 1-10 carbon atoms, and other polyalphaolefins such as

polydecene, isobutene. Non-volatile hydrocarbons include, for example, mineral oil, liquid paraffins. C2 to C8 paraffins, isoparaffins, squalane, squalene or petrolatum.

The fluororesin can be used to enhance the photoprotective effect of virtually any sunscreen agent to be applied topically. Accordingly, the sunscreen agent can be a wide variety of conventional sunscreen agents, including both organic and inorganic sunscreen agents. Other suitable sunscreening agents include for example, p-aminobenzoic acid, its salts and its derivatives, anthrilates, salicylates, water soluble sunscreens such as Eusolex 232, oil soluble sunscreens, such as octyl methoxycinnamate and other cinnamic acid derivatives, dihydroxycinnamic acid derivatives, trihydroxycinnamic acid derivatives, paramethoxy-ethylhexyl ester cinnamate, hydrocarbons such as diphenylbutadiene, stilbene, particulate sunscreens such as zinc oxide and titanium dioxide. dibenzalacetone and benzalacetophenone, naphtholsulfonates, dihydroxy-naphthoic acid and its salts, o- and p-hydroxy-biphenyldisulfonates, coumarin derivatives, diazoles, quinine slats, quinoline derivatives, benzophenones or hydroxy- or methoxy- substituted benzophenones, benzophenone carbonate, uric and vilouric acids. tannic acid and its derivatives. hydroquinone. 4-isopropyldibenzoylmethane. butylmethoxydibenzoyl-methane. etocrylene. octocrylene. 2-ethylhexysalicylate, glyderyl p-aminobenzoate, 3,3,5-trimethylcyclohexysalicylate, methylanthranilate. menthyl anthranilate, p-dimethyl-aminobenzoic acid or aminobenzoate, 2-ethylhexyl p-dimethylamino-benzoate, 2-phenyl-benzimidazole-5-sulfonic acid, 2-(p-dimethylaminophenyl)-5-sulfonicbenzoxazoic acid and mixtures of these compounds.

In a particularly preferred embodiment. the sunscreen agent is an organic sunscreen such as octyl methoxycinnamate or benzophenone. More preferably, the organic sunscreen is octyl methoxycinnamate. The amounts will vary depending on the sunscreen that is chosen and the desired SPF. Preferably, the amount of organic sunscreen is from about 1 to about 10 percent of the weight of the composition. SPF is a value which measures the amount of photoprotection against erythema that a sunscreen provides. The number is based on the minimal erythemal dose ("MED"), the least exposure dose at a specific wavelength that will elicit a delayed response in erythema. The MED is an indicator of how much energy reaches the skin and the responsiveness of the skin to the radiation to which it is subjected. The SPF value is calculated by dividing the MED of protected skin by the MED of unprotected skin.

In particular, the present invention provides sunscreen compositions of varying SPF values. Typical sunscreens which have an SPF value in the range of about 15 to about 25 are formulated to contain about 8 to 12 percent of titanium dioxide to achieve an SPF of about 25

and about 5 to 6 percent to achieve an SPF of about 15 in addition to other inorganic sunscreen agents. In contrast, according to the present invention a sunscreen formulation of about 25 SPF contains about 1 to 2 percent titanium dioxide in addition to other inorganic sunscreen agents, a reduction of about 25 percent. Accordingly, in the present invention, the sunscreen agent is present in an amount of from about 1 to about 20 percent by weight of the total composition. Preferably, the sunscreen agent is about 3 to about 10 percent.

Another advantage of combining the submicron fluororesin with sunscreen agents is the ability to reduce the amount of irritation experienced with the use of sunscreens. The irritation caused by excessive amounts of sunscreen agents used is commonly known in the art. By being able to reduce the amount of sunscreen agent and in particular the inorganic sunscreen agent, titanium dioxide, and the organic sunscreen agent, octyl methoxycinnamate, the amount of irritation is reduced.

The compositions of the present invention may also comprise other optional components, depending on the intended end use. These include, but are not limited to, oil soluble colorants (such as D&C Green #6); antioxidants (such as BHT); chelating agents (such as disodium EDTA); dispersion stabilizers or thickeners such as clay, silica, fluorinated surfactants, and other general surfactants, preservatives (such as methyl paraben); fragrances (such as pinene); flavoring agents (such as sorbitol); humectants (such as glycerine); waterproofing agents (such as PVP/eicosene copolymer); oil-soluble film formers (such as hydrogenated C-9 resin); cationic polymers (such as polyquaternium 10); anionic polymers (such as xanthan gum); vitamins (such as tocopherol); and the like.

The benefit of combining the submicron fluororesin with a sunscreen agent is obtained in any type of a water-in-oil or oil-in-water emulsion, or anhydrous composition. The compositions of the present invention can be used in any type of makeup or in any type of skin or sun care product. Typical examples include foundations, eyeshadows, eyeliners, mascaras, blushes, powders, lipsticks, lipglosses, lip paints, oil control skin mattifiers, and sunscreen lotions. The present invention further comprises pharmaceutically or cosmetically acceptable sunscreen carrier materials selected as appropriate for the form and aesthetic characteristics desired for the composition being formulated. Suitable carrier materials useful for sunscreen compositions as described herein are well known in the art, and their selection is readily made by one of ordinary skill in the art.

The present invention also relates to methods for providing photoprotection to the skin. The methods comprise topically applying to the skin a safe and photoprotectively effective

amount of the compositions according to the present invention. In addition, the fluororesin sunscreen compositions of the present invention can be used to completely eliminate the use of inorganic sunscreens. The sunscreen compositions can be used in categories other than cosmetic or pharmaceutical, for example, the compositions of the present invention can be used in paints and coatings applied to surfaces.

The invention is further illustrated by the following non-limiting examples.

EXAMPLE 1

A composition, having an SPF of about 15, according to the present invention is prepared as follows:

Material	Weight %
Phase I	
Purified Water	35.0
Alkoxylated Alcohol	1.8
Butylene Glycol	4.5
Phenoxyethanol	1.0
Disodium EDTA	0.2
Sodium Chloride	0.8
Sucrose	2.0
Phase II	
Octyl Methoxycinnamate	8.0
Cyclomethicone	7.0
BHT	0.3
Linoleic Acid	0.4
Bishydroxyethyl Biscetyl Malonamide	0.4
Alkyl Benzoate	7.0
Dimethicone	4.0
PEG-30 Dipolyhydroxystearate	1.0
Phase III	
PTFE	2.8
Polyisobutene	11.0
Phase IV	
Cetyl Dimethicone Copolyol	8.0
Cyclomethicone	4.8
Tocopheryl Acetate	0.5

To prepare the composition, Phase I and II materials are combined by mixing with a homogenizer at 3600 rpm; this mixture is then heated to 70°C and mixed for about five minutes. After homogenization, the emulsion is allowed to cool. Phase III materials, including the PTFE provided by Shamrock Technologies Inc., Newark, NJ, are combined with Phase I and II materials by mixing. Finally, the remaining Phase IV materials are added and mixed together.

EXAMPLE II

A composition according to Example I, containing 7.5 percent octyl methoxycinnamate as the sunscreen agent, is studied with and without fluororesin to determine the amount of boost in SPF.

A panel of 5 individuals is selected to participate in the test. The panelists have Fitzpatrick type I-II skin. Particularly, the skin on the backs of the panelists are evenly colored and free of blemishes, stretch marks and discolorations. A standard SPF protocol is followed and uses a Berger Solar Simulator. The MED of the panelists is determined. Two areas are marked on the backs of the panelists. A composition is prepared according to Example I above containing 7.5 percent octyl methoxycinnamate and 2.8 percent fluororesin is applied to one area and a composition containing the same amount of 7.5 percent of octyl methoxycinnamate without fluororesin (i.e., the control) is applied to the second area. Both applications are in an amount of about 2 mg/cm^2 and allowed to dry for about 15 to 20 minutes. These areas are exposed to about 10 to 15 times the previously determined MED. The SPF value for formula prepared according to the present invention shows an increase in the SPF.

What we claim is:

1. A sunscreen composition having enhanced photoprotective effect comprising a sunscreen agent in combination with a fluororesin polymer having a submicron particle size.

2. The composition of claim 1 in which said fluororesin has an average particle size of about 200 to about 1200 nm.

3. The composition of claim 2 in which said fluororesin is polytetrafluorethylene.

4. The composition of claim 3 in which said fluororesin is present in an amount of from about 0.1 to about 10.0 percent by weight of the total composition.

5. The composition of claim 1 in which said fluororesin is present in an amount of from about 0.2 to about 5.0 % by weight and said sunscreen agent is present in an amount of from about 1 to about 20 percent by weight of the total composition.

6. The composition of claim 1 in which said sunscreen agent is present in an amount of from about 1 to about 20 percent by weight of the total composition.

7. The composition of claim 6 in which said sunscreen agent is organic, inorganic or a combination thereof.

8. The composition of claim 7 in which said sunscreen is organic.

9. The composition of claim 8 in which said sunscreen agent is octyl methoxycinnamate.

10. The composition of claim 7 in which said sunscreen agent is inorganic.

11. The composition of claim 10 in which said sunscreen agent is titanium dioxide.

12. The composition of claim 1 in which said composition further comprises an oil component.

13. The composition of claim 12 in which said oil component is a hydrophobic vehicle.

14. The composition of claim 13 in which said hydrophobic vehicle is a hydrocarbon.

15. The composition of claim 14 in which said hydrocarbon is polyisobutene.

16. The composition of claim 1 which has an SPF from about 15 to about 25.

17. The composition of claim 1 which has an SPF of at least about 15.

18. A cosmetic or pharmaceutical composition comprising from about 0.1 to about 10.0 percent of a fluororesin polymer having a submicron particle size dispersed in a hydrophobic vehicle in combination with a sunscreen agent.

19. A cosmetic or pharmaceutical composition comprising from about 0.1 to about 10.0 percent of a fluororesin polymer having a submicron particle size dispersed in a hydrocarbon vehicle in combination with an organic sunscreen agent.

20. A method of boosting the SPF of a sunscreen composition comprising applying to the skin the composition of claim 1.

21. A method of boosting the SPF of a sunscreen composition comprising applying to the skin the composition of claim 18.

22. A method of boosting the SPF of a sunscreen composition comprising applying to the skin the composition of claim 19.

23. A method of decreasing the irritation on the skin caused by a sunscreen agent comprising applying to the skin the composition of claim 1.

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 99/29259

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K7/42

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 827 507 A (K. OSHIMA ET AL.) 27 October 1998 (1998-10-27) claim 1; examples 3,5,15	1
A	US 5 607 979 A (M. MCCREERY) 4 March 1997 (1997-03-04)	1
A	EP 0 704 205 A (L'OREAL) 3 April 1996 (1996-04-03) claim 1; example 1B	1
A	WO 98 46200 A (SHAMROCK TECHNOLOGIES INC.) 22 October 1998 (1998-10-22) page 2, line 3-5; claim 1; example 9	1
A	US 5 622 690 A (R. POTTER ET AL.) 22 April 1997 (1997-04-22) table III	1

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 April 2000	18/04/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Glikman, J-F

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter. nal Application No
PCT/US 99/29259

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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JP 09263523 A	07-10-1997	NONE	

INTERNATIONAL SEARCH REPORT

Inter xnal Application No
PCT/US 99/29259

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE CHEMICAL ABSTRACTS 'Online! STN abstract 127: 311 367, XP002134737 abstract & JP 09 263523 A (SHISEIDO CO., LTD) 7 October 1997 (1997-10-07)	1

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

Paper 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARTIN BRAHM, EBERHARD ARNING
LUTZ SCHMALSTIEG, HARALD MERTES and JURGEN SCHWINDT

Appeal 1997-3039
Application 08/436,939[1]

Before: McKELVEY, Senior Administrative Patent Judge, and SCHAFER and LEE, Administrative Patent Judges.

McKELVEY, Senior Administrative Patent Judge.

MEMORANDUM OPINION and ORDER
Decision on appeal under 35 U.S.C. § 134

Upon consideration of the record, including the Appeal Brief (Paper 9), the Examiner's Answer (Paper 10) and the Reply Brief (Paper 11), it is

ORDERED that the examiner's rejection of claims 1-15 as being unpatentable under 35 U.S.C. § 103 over Slack and

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[1] Application for patent filed 8 May 1995. Applicants claim priority under 35 U.S.C. § 119 of German application P 44 177 45.3, filed 20 May 1994. The real party in interest is Bayer AG.

Brahm (alternatively published Canadian Patent Application 2,155,684) is reversed.

The broadest claim on appeal is claim 1, which reads:

> An olefinically unsaturated polyisocyanate containing allophanate groups and having:
>
> a) an NCO [isocyanate] content of 6 to 20% by weight,
>
> b) a content of olefinic double bonds corresponding to an iodine value of 15 to 150,
>
> c) a content of hydrocarbon chains containing 12 to 30 carbon atoms of 100 to 700 mg/g and
>
> d) a content of allophanate groups (expressed as $C_2NH_2O_3$, molecular weight = 101) of 10 to 300 mg/g.

Slack describes polyisocyanates which are similar to those claimed which can be made from a wide variety of hydroxy-containing compounds (col. 3, line 29 through col. 5, line 28). Included among the hydroxy-containing compounds are "fatty alcohols having 10 to 20 carbon atoms" (col. 3, lines 56-57). The difference between claim 1 and Slack is that Slack does not explicitly describe the use of a fatty alcohol having "olefinic double bonds."

The examiner found, inter alia, that fatty alcohols having 10 to 20 carbon atoms includes fatty alcohols with olefinic double bonds. Accordingly, the examiner reasons that applicants have selected one of many hydroxy-containing compounds described as useful for making the polyisocyanates containing allophanate groups. Assuming arguendo the correctness of the examiner's finding, the rejection cannot be sustained on the basis of the rationale of the Federal Circuit in In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) (fact that claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious).

Alternatively, the examiner cites Brahm and published Canadian Patent Application 2,115,684 (equivalent documents) for the proposition that it is known to react isocyanates with fatty alcohols having olefinic unsaturation (Brahm, col. 3, lines 49-54). Based on what is taught by Brahm, the examiner reasons that it would have been obvious to use a fatty alcohol having olefinic unsaturation in the process described by Slack. The examiner's reasoning is based on impermissible hindsight. The reaction temperature described by Slack (at

least 150°C; col. 2, lines 31-32) is higher than the reaction temperature described by Brahm (10 to 140°C; col. 4, line 14). Brahm is not concerned with making products having allophanate groups. Based on the record before us, we are unable to find any reason, suggestion, motivation or teaching to use the fatty alcohols having olefinic unsaturation described in Brahm in the process described by Slack.

There is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time of the invention. The relevant inquiry is whether there is a reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the teachings of the references, and that would also suggest a reasonable likelihood of success. Such a suggestion or motivation may come from the references themselves, from knowledge by those skilled in the art that certain references are of special interest in a field, or even from the nature of the problem to be solved. Smith Industries Medical Systems, Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1420-21 (Fed. Cir. 1999). In this case, the examiner has failed to

identify a motivation, teaching or suggestion to combine the prior art in the manner suggested in the examiner's answer.

REVERSED.

FRED E. McKELVEY, Senior Administrative Patent Judge	)
RICHARD E. SCHAFER Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
JAMESON LEE Administrative Patent Judge	)

Appeal 1997-3039
Application 08/436,939

cc (via First Class Mail):

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Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD L. ANDERSON
and
BRUCE B. RANDOLPH

Appeal No. 1998-2622
Application No. 08/530,684

ON BRIEF

Before PAK, WALTZ, and PAWLIKOWSKI, **Administrative Patent Judges**.

WALTZ, **Administrative Patent Judge**.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 through 11, which are the only claims pending in this application.

Appellants disclose that processing of an alkylation reactor effluent produced by the catalytic alkylation of olefins by isoparaffins using a hydrogen halide catalyst in a

sulfone diluent requires the subsequent removal of the sulfone from the hydrocarbon stream, i.e., reduction of the amount of sulfone from about 4000 ppmw to less than about 100 ppmw (specification, pages 1-2). According to appellants, their invention is directed to a method of removing sulfone[1] from a liquid hydrocarbon stream including the steps of mixing the liquid hydrocarbon stream with liquid hydrofluoric acid (HF) and separating this admixture into a hydrocarbon phase and an acid phase, where the hydrocarbon phase has a concentration of sulfone less than the concentration of sulfone in the liquid hydrocarbon stream (Brief, page 2).

Claim 1 is illustrative of the subject matter on appeal and a copy of this claim is reproduced below:

> 1. A method for removing sulfone from a liquid hydrocarbon stream, said liquid hydrocarbon stream having a concentration of sulfone in the range of from about 150 ppmw to about 4000 ppmw, said method comprises the steps of:
>
> mixing within a mixing zone said liquid hydrocarbon stream with a liquid acid, said liquid acid comprising HF, to form an admixture of said liquid hydrocarbon stream and said liquid acid;

---

[1]Appellants disclose a general formula defining the sulfones suitable for use in their invention (specification, page 9, l. 11 *et seq.*).

passing said admixture to a phase separation zone wherein said admixture is separated into at least two liquid phases including a hydrocarbon phase, having

a concentration of sulfone less than said concentration of sulfone in said liquid hydrocarbon stream, and an acid phase, having a concentration of sulfone.

The examiner has relied upon the following reference as evidence of obviousness:

Siskin et al. (Siskin) 3,957,628 May 18, 1976

Claims 1 through 11 stand rejected under 35 U.S.C. § 103 as unpatentable over Siskin (Answer, page 3). We *reverse* the examiner's rejection for reasons which follow.

OPINION

The examiner finds that Siskin teaches a process for removing organic sulfur compounds including those containing oxygen from a liquid hydrocarbon feedstock comprising the steps of contacting the liquid hydrocarbon feedstock with liquid HF in any suitable apparatus followed by separation of the product into two phases using any suitable method, where one phase is a substantially sulfur-free hydrocarbon raffinate and the second phase is a sulfur-containing HF extract

(Answer, pages 3-4). The examiner further finds that the difference between Siskin and the claimed subject matter is that Siskin does not specifically teach removal of sulfones (*id.* at page 4).

From these findings, the examiner concludes that it would have been obvious to one having ordinary skill in the art at the time the invention was made "to have modified the process of Siskin to specifically remove sulfone from a hydrocarbon feedstock because Siskin has taught the removal of a general class of organic sulfur compounds containing oxygen which would be recognized by an artisan skilled in the art to include sulfone and with the expectation of achieving similar results." (*Id.*).

Siskin teaches the "virtual quantitative removal of organic sulfur . . . compounds" by contacting a liquid hydrocarbon feedstock with hydrogen fluoride (col. 1, ll. 57-61). Irregardless of the interpretation of the Siskin disclosure of removing organic groups such as oxygen and nitrogen, we agree with the examiner that removal of "organic sulfur compounds" by Siskin is generic to the claimed removal

of sulfones (see col. 2, l. 51-col. 3, l. 14). However, the mere generic disclosure of removing organic sulfur compounds from a liquid hydrocarbon feedstock is not sufficient to establish a *prima facie* case of obviousness. *See In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994); *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992). There must be a showing of a suggestion or motivation to modify the teachings of the reference to the claimed subject matter in order to support an obviousness conclusion. *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996). This suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996).

Siskin itself only suggests that the organic sulfur compounds may include sulfides, mercaptans, disulfides and

thiophenes (col. 2, ll. 63-65).[2] According to appellants, a recently discovered alkylation catalyst mixture contains a hydrogen halide component in a sulfone diluent. After use of this catalyst mixture in the alkylation of olefins by isoparaffins, the alkylate product contains a concentration of sulfone which is undesirable and must be removed because of the use of the alkylate as a gasoline blending material (specification, pages 1-2). On this record, the examiner has not shown, by convincing reasoning or evidence, that sulfones would have been present in the liquid hydrocarbon feedstock of Siskin. Siskin discloses a process for refining sulfur, oxygen and nitrogen contaminated hydrocarbon feedstocks (col. 1, ll. 6-8). Siskin discloses that sulfur compounds are present as impurities in the hydrocarbon feedstocks and must be removed since these impurities tend to poison or deactivate the acidic catalysts used in subsequent reactions such as reforming, alkylation, isomerization and the like (col. 1, ll. 19-29). Therefore, on this record, the examiner has failed to

---

[2]All of these classes of compounds disclosed by Siskin contain sulfur only attached to carbon or hydrogen, i.e., they do not contain the $-SO_2-$ functional group.

show any suggestion or motivation why one of ordinary skill in the art would have modified the process of Siskin to remove sulfone compounds.

For the foregoing reasons, we determine that the examiner has not established a *prima facie* case of obviousness in view of the reference evidence. Accordingly, the rejection of claims 1 through 11 under 35 U.S.C. § 103 as unpatentable over Siskin cannot be sustained.

The decision of the examiner is reversed.

REVERSED

CHUNG K. PAK Administrative Patent Judge	)	
THOMAS A. WALTZ Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
BEVERLY A. PAWLIKOWSKI Administrative Patent Judge	)	

TAW:hh

Appeal No. 1998-2622
Application No. 08/530,684

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Paper No. 58

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MICHAEL DORSCHUB, PAUL HABERMANN, GERHARD SEIPKE and EUGEN UHLMANN

Appeal No. 2001-1586
Application No. 08/402,394

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER and ADAMS, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from an examiner's final rejection of claims 21 through 23, 25 through 27 and 31. Subsequently, claims 33 through 42 were added. Thus, 21 through 23, 25 through 27, 31 and 33 through 42 are before us for review.

Claim 33 and 42 are representative of the subject matter on appeal and reads as follows:[1]

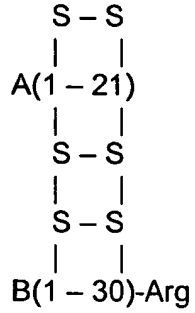
33. A compound of the formula I

B(1-30)-Arg-A(1-21)

(I)

wherein A(1-21) and B(1-30) denote the A and B chains of human insulin.

42. A method for the preparation of a mono-Arg-insulin compound of the formula II



(II)

in which A(1-21) and B(1-30) denote the A and B chains of human insulin and the –S-S- bridges are positioned as in insulin, which comprises:

(a) expressing a DNA sequence encoding a mini-proinsulin compound of the formula:

B(1-30)-Arg-A(1-31)

in a yeast; and

(b) cleaving said mini-proinsulin compound with trypsin.

The references relied upon by the examiner are:

Mai et al. (Mai)	5,087,564	Feb. 11, 1992
Markussen et al. (Markussen '212)	4,916,212	Apr. 10, 1990
Grau (Grau '684)	4,801,684	Jan. 31, 1989
Grau (Grau '332)	4,639,332	Jan 27, 1987

[1] We note that claim 42(a) requires the use of the compound B(1-30)-Arg-A(1-31) instead of B(1-30)-Arg-A(1-21). We view "A(1-31)" in the claim to be a typographical error as all references to this compound in the original disclosure of this application state that the A chain is depicted as "A(1-21)." Claim 21 also contains this apparent error. Our consideration of the issues raised in this appeal has been based upon claim 42(a) requiring the use of the compound B(1-30)-Arg-A(1-21). Note counsel's statement at page 8 of the Appeal Brief "the common subject matter to every pending claim is the compound of formula B(1-30)-Arg-A(1-21)."

Markussen et al. (Markussen EPO)	EPO 163,529	Dec. 4, 1985
Goeddel et al. (Goeddel)[2]	EPO 0,05,5945	Jul. 14, 1982

A reference of record discussed by this merits panel is:

Thim et al. (Thim)	EPO 0,195,691	Sep. 24, 1986

The claims stand rejected as follows:

Claims 21 and 33 through 36 under 35 U.S.C. § 103(a). The examiner relies upon Markussen '212 or Markussen EPO, Godeddel, Grau '684 and Grau '332 as evidence of obviousness,

Claims 25, 37 and 38 under 35 U.S.C. § 103(a) with the examiner relying upon Markussen '212 or Markussen EPO, Godeddel, Grau '684, Grau '332 and Mai as evidence of obviousness,

Claims 22, 23, 40 and 41 under 35 U.S.C. § 103(a) with the examiner relying upon Markussen '212 or Markussen EPO, Godeddel, Grau '684 and Grau '332 as evidence of obviousness,

Claims 26, 27, 31 and 32 under 35 U.S.C. § 103(a) with the examiner relying upon Markussen '212 or Markussen EPO, Godeddel, Mai, Grau '684 and Grau '332 as evidence of obviousness, and

Claims 39 and 42 under 35 U. S. C. § 103(a) with the examiner relying upon Markussen '212 or Markussen EPO, Grau '684 and Grau '332 as evidence of obviousness.

---

[2] While this reference is not listed at page 3 of the Examiner's Answer as being relied upon, it is in fact used as evidence of obviousness in rejecting the claims in the Examiner's Answer as it was in the final rejection. We view the examiner's failure to list this reference as an inadvertent oversight.

We reverse. In addition, we raise other issues for the examiner and appellants to consider.

DISCUSSION

The formation of human insulin is described in Thim at page 2, lines 5-21 as follows:

> Human insulin consists of two peptide chains, the A-chain containing 21 amino acid residues and the B-chain containing 30 amino acid residues. The A- and B-chain are joined together by two disulfide bridges connecting the cysteinyl residue at A7 to B7 and A20 to B19, respectively. A third disulphide bridge is formed between the cysteinyl residues A6 and A11.
>
> Human insulin is produced in vivo in the pancreas in the form of preproinsulin. Preproinsulin consists of a prepeptide of 24 amino acid residues followed by proinsulin containing 86 amino acid residues in the configuration: prepeptide-B-Arg-Arg-C-Lys-Arg-A in which C is the C-peptide of 31 amino acid residues.
>
> During excretion from the islet cells the prepeptide is cleaved off and proinsulin then folds to a structure in which disulfide bridges are formed. The C-peptide is then excised proteolytically to give mature human insulin.

The compound set forth in claim 33 on appeal is termed a "mini-proinsulin" by appellants and is stated to be useful in preparing human insulin Arg^{B31} –OH (mono-Arg insulin). Specification, page 1. This compound is also described in Grau '332. Id. Further, the compound of claim 33 is stated to show insulin activity itself. Id. As seen from claim 42 reproduced above, mono-Arg insulin can be prepared by simply treating the compound of claim 33 with trypsin.[3]

Key in deciding the issues raised in all of the obviousness rejections before us for review is determining whether the compound of claim 33 is novel and unobvious. If the compound of claim 33 is novel and unobvious, all of the obviousness rejections fall

[3] This again assumes the reference in claim 42(a) to A(1-31) is a typo.

since the method claims on appeal require the use of this compound. Also, nucleic acid sequence claim 34, vector claim 35, host cell claim 36 and fusion protein claim 37, would also be patentable if the compound of claim 33 is determined to be novel and unobvious.

The examiner has relied upon Markussen '212 and Markussen EPO in the alternative in stating the rejection of claim 33. The two Markussen patent documents appear to be equivalent, or at the least, the examiner has not pointed to any significant difference in their disclosures. As such, we shall limit our consideration of the issues raised in this appeal to Markussen '212. In similar fashion, the examiner has not distinguished in any meaningful sense between Grau '684 and Grau '332. Thus, we shall limit our consideration of patentability of claim 33 in light of Grau '332.

As we understand the examiner's position in regard to the patentability of the compound of claim 33 it is as follows. Markussen '212 describes a genus of mini-proinsulin precursors at column 2, line 63-column 3, line 18 as follows:

> According to a first aspect of the present invention there is provided a DNA-sequence encoding insulin precursors of the formula
>
> B(1-29)-(X_n-y)$_m$-A(1-21) I
>
> wherein X_n is a peptide chain with n amino acid residues, Y is Lys or Arg, n is an integer from 0 to 33, m is 0 or 1, B(1-29) is a shortened B-chain of human insulin from Phe^{B1} to Lys^{B29} and A(1-21) is the A chain of human insulin, with the proviso that the peptide chain –X_n-Y- does not contain two adjacent basic amino acid residues (i.e., Lys and Arg).
>
> Preferred insulin precursors of the above formula I are B(1-29)-A(1-21), i.e. m=0 in formula I, and compounds with a relative short bridging chain between the B(1-29)- and the A(1-21)-chain.
>
> When m=1, then n is preferably 1-33, more preferably 1-15, 1-8 or 1-5 and most preferably 1-3 or 1-2. X may preferably be selected from the group consisting of Ala, Ser and Thr, the individual X's being equal or different. Examples of such preferred compounds are B(1-29)-Ser-Lys-A(1-21) and B(1-29)-Ala-Ala-Lys-A(1-21).

The examiner points out at page 5 of the Examiner's Answer[4] that the generic structural formula of the insulin precursors does encompass the compound of claim 33 if X is Thr, n is 1 and Y is Arg.

While not explicitly stated in the Examiner's Answer, we believe the examiner was aware of cases such as In re Baird, 348 F.2d 974, 29 USPQ2d 1550 (Fed. Cir. 1994) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992) that stand for the proposition that disclosure of a chemical genus does not necessarily render obvious any species that happens to fall within that genus. Thus, the examiner articulates a so-called motivation why one of ordinary skill in the art would select the compound of claim 33 from the genus of proinsulin compounds described in Markussen '212.

The examiner's motivation to do so involves the description in Grau '332 that "the derivative insulin-Arg^{B31}-OH in crystalline form is exceptionally stable to further tryptic degradation." Grau '332, column 2, lines 10-12. We believe the examiner's position is that once one of ordinary skill in the art understands that insulin-Arg ^{B31}-OH is a desired insulin derivative, that hypothetical person would also understand from reading the generic disclosure of the proinsulin compounds described in Markussen '212 that the species of that genus wherein X is Thr, n is 1 and Y is Arg may be cleaved by trypsin and thus produce the desired insulin-Arg ^{B31}-OH. In our view, the examiner's position is based upon impermissible hindsight.

We must view the applied prior art and the examiner's stated reasons for combining the references apart from appellants' disclosure of the present invention

[4] The pages of the Examiner's Answer are misnumbered. Pages 1 and 2 are correctly numbered while page 3 contains no page number and page 4 is stated to be page number 2 with that mistake continuing

since it is teachings in the references or knowledge generally available in the art that must suggest the desirability of combining the teachings in order to arrive at the claimed subject matter. Here, the examiner's reasoning is premised upon one of ordinary skill in the art reading the disclosure of the genus of proinsulin compounds in Markussen '212 throught the lens of Grau '332. However, we do not find the lens of Grau '322 to be as sharply focused as does the examiner.

The examiner has not analyzed Grau '332 in regard to the intermediates taught or suggested by the reference that would be useful in preparing the final products of the reference such as insulin-Arg ^{B31}-OH. If the selection of the compound of claim 33 to use as the intermediate in preparing insulin-Arg ^{B31}-OH would have been obvious, it seems that it would have been obvious from a consideration of Grau '322 alone on the basis of working backwards from a given desired end product and preparing a list of intermediate insulin derivatives which would result in the desired end product after tryptic digestion. For example, Example 2 of Grau '322 uses monkey preproinsulin to form insulin-Arg ^{B31}-OH. It is unclear how large the list of possible intermediates is, as the examiner's analysis did not follow this path. It may be that, viewed in this light, the list of possible insulin intermediates that are capable of forming insulin-Arg ^{B31}-OH by way of tryptic digestion is quite large. If so, one is put in the same position as one is in viewing the large genus of insulin compounds described by Markussen '322. Instead of analyzing Grau '322 in this light, the examiner's analysis jumps immediately to apparently the only species of the possible millions of compounds generically described

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on throughout the remainder of the document. References to page numbers of the Examiner's Answer are based upon the actual page numbers of the record document.

in Markussen '212 as the intermediate to use in Grau '322 to form insulin-Arg^{B31}-OH. We think the examiner's leap from Grau '332 to Markussen '212 was guided by appellants' disclosure of the present invention instead of the references themselves. The examiner's analysis bespeaks more of an impermissible hindsight analysis instead of a reasoned explanation of why the applied art suggests the compound of claim 33. Thus, we do not find that the examiner has properly established a prima facie case of obviousness.

As set forth above, this finding mandates reversal of all obviousness rejections set forth in the Examiner's Answer.

OTHER ISSUES

Viewing the disclosure of Markussen '212 while focused solely on the subject matter of claim 33 on appeal, we believe Markussen '212 is more relevant in determining the patentability of the compound of claim 33 than either the examiner or appellants have recognized on this record.

Markussen '212 does describe a genus of insulin precursors at column 2, line 63-column 3, line17, which encompasses a large number of compounds. As indicated above, Jones and Baird stand for the proposition that a broad chemical genus such as that described in Markussen '212 does not necessarily render obvious any specific species encompassed therein. However, that is not the end of the matter. In In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962) the court was confronted with a similar factual situation. The court stated that even though Petering's claimed compounds were encompassed by a broad generic prior art disclosure, the court concluded that the broad disclosure by itself described the claimed compounds within

the meaning of 35 U.S.C. § 102(b). Id., 301 F.2d at 681, 133 USPQ at 279. However, the court went on to describe what it termed "specific preferences" for the substituents of the chemical compounds described in the applied reference, Karrer. The court concluded that it was their "opinion that the pattern of Karrer's specific preferences in connection with his generic formula constitutes a description of a definite and limited class of compounds." Id. 301 F.2d at 681, 133 USPQ at 280. The court concluded:

> We think the Karrer patent, as a printed publication, describes to one skilled in this art not only the broad class but also this much more limited class within that broad class, and we think it is immaterial that Karrer did not expressly spell out the limited classes as we have done here, it is our opinion that one skilled in this art would, on reading the Karrer patent, at once envisage each member of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class as we have done here.

Id. .

We believe the examiner and appellants need to read Markussen '212 very carefully in light of Petering. Markussen '212 states that preferred insulin precursors includes those where m=1, n is most preferably 1-3 or 1-2 and that X is preferably Ala, Ser and Thr, X being equal or different. Thus, it may be that Markussen '212 is describing a very limited subgenus of compounds as follows:

The structural formula B(1-29)-$(X_n$-$Y)_m$-A(1-21) wherein m=1, n =1 or 2, X = Ala, Ser, Thr, X being equal or different, Y = Lys or Arg defines two subgenus, i.e.,

B(1-29) (X_n-Lys) A(1-21) and B(1-29) (X_n-Arg)A(1-21) wherein n = 1 or 2, X = Ala, Ser, Thr with X being equal or different.

The second subgenus consists of the following compounds:

1. B(1-29)	(Ala-Arg)	A(1-21)
2. B(1-29)	(Ser-Arg)	A(1-21)
3. B(1-29)	(Thr-Arg)	A(1-21)
4. B(1-29)	(Ala-Ala-Arg)	A(1-21)
5. B(1-29)	(Ala-Ser-Arg)	A(1-21)
6. B(1-29)	(Ala-Thr-Arg)	A(1-21)
7. B(1-29)	(Ser-Ala-Arg)	A(1-21)
8. B(1-29)	(Ser-Ser-Arg)	A(1-21)
9. B(1-29)	(Ser-Thr-Arg)	A(1-21)
10. B(1-29)	(Thr-Ala-Arg)	A(1-21)
11. B(1-29)	(Thr-Ser-Arg)	A(1-21)
12. B(1-29)	(Thr-Thr-Arg)	A(1-21)

Amino acid residue 30 of the B chain of human insulin is Thr. See, e.g., Figure 1 of Thim. Thus, compound 3 enumerated in the above table is the compound required by claim 33 on appeal, i.e., B(1-30)-Arg-A(1-21).

Upon return of the application, the examiner and appellants should carefully review the disclosure of the insulin precursors described in Markussen '212 in light of the guidance provided by In re Petering. If in fact one of the preferred subgenera of Markussen '212 consists of the 12 compounds set forth in the above table which includes the compound of claim 33, it may be reasonable for the examiner to conclude

that Markussen '212 describes the compound required by claim 33 with the specificity required by 35 U.S.C. § 102, i.e., Markussen '212 anticipates claim 33.

We are aware that a substantial portion of appellants' position in regard to the examiner's rejection is premised upon the prosecution history of Markussen '212. For example, appellants argue at the Reply Brief, page 6:

> Thus. Markussen was able to overcome the prior art by arguing that the shortened B-chain was what gave his invention its novelty and superiority and argues that a B30 Threonine residue is never present in the precursor. The Office cannot now say that "X" is equivalent to the B30 Threonine. This would completely ignore all of the arguments used to overcome the prior art, thereby invalidating the Markussen patent.

These arguments are more relevant in determining the scope of the Markussen '212 claims in an inter partes enforcement action than in determining the relevance the disclosure of Markussen '212 has in determining the patentability of claims pending ex parte before the USPTO. As seen, this argument is couched in terms of the patentability of Markussen's "invention," not the claims of Markussen '212. An inventor may describe his invention in both broad and narrow terms in the specification of the application and in the course of prosecution disavow the broader invention by way of amendment or argument. The fact that a proper construction of the claims in an issued patent[5] may result in a claim scope narrower than the broader description of the invention in the specification does not mean that the broader description of the invention disappears from the patent. Rather, the broader description remains there and must be evaluated for what it means to one of ordinary skill in the art in the context of determining the patentability of claims pending in this application. We do not

understand appellants' position to be that with appropriate selection of variables, Markussen '212 does not literally describe the compound of claim 33. Rather, appellants would have the disclosure ignored or wished away by analyzing the arguments made on behalf on Markussen in procuring the patent.

If the examiner determines that Markussen '212 describes the compound of claim 33, the examiner should revisit the issue of the patentability of the method claims pending in this application. It may be that once it is determined that Markussen '212 contains a sufficiently specific description of the compound of claim 33 so as to be anticipatory, a person of skill in this art focused on that compound would understand that due to its amino acid sequence, the compound is amenable to tryptic cleavage in order to form insulin-Arg^{B31}-OH which Grau '332 describes as possessing beneficial properties.

REVERSED

William F. Smith Administrative Patent Judge	)
	) BOARD OF PATENT
Toni R. Scheiner Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
Donald E. Adams Administrative Patent Judge	)

[5] We take no position on appellants' arguments based upon the prosecution history of Markussen '212 in regard to their accuracy or correctness.

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ELD

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PATRICIA LEMANN, ANNICK COLLETTE and ISABELLE BARA

Appeal No. 2006-0391
Application No. 10/366,371

HEARD: March 7, 2006

Before ELLIS, ADAMS and GRIMES, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the examiner's final rejection of claims 1-4, 7-37, 40-69, 76 and 77. Claims 5, 6, 38, 39 and 70-75 have been canceled.

Claims 1, 13 and 17 are representative of the subject matter on appeal and reads as follows:

1. An anhydrous composition comprising at least one silicone oil, at least one pigment, and at least one oxyalkylenated silicone substituted at the α and ω positions, wherein said anhydrous composition contains less than 1% by weight of water with respect to the total weight of the composition.

13. The composition according to Claim 1, wherein said at least one pigment is chosen from titanium, zirconium and cerium dioxides, zinc, iron and chromium oxides, ferric blue, pearlescent agents, carbon black, barium, strontium, calcium, aluminium lakes, pigments coated with silicone compounds, pigments coated with polymers, pigments coated with amino acids, and pigments coated with a mixture chosen from silicone compounds, polymers, and amino acids.

17. The composition according to Claim 13, wherein said polymers are polyethylenes.

The references relied upon by the examiner are:

Nojima	5,650,139	Jul. 22, 1997
Barone et al. (Barone)	5,034,216	Jul. 23, 1991

The claims stand rejected as follows:

I. Claims 1-4, 7-16, 18-37, 40-49, 51-69, 76 and 77 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nojima.

II. Claims 17 and 50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nojima and Barone.

We have carefully considered the respective positions of both the appellants and the examiner and find ourselves in substantial agreement with that of the appellants. Accordingly, we reverse.

Background and Discussion

The anhydrous compositions recited in claim 1, above, are said to be useful for cosmetic, dermatological, hygienic or pharmaceutical purposes. Specification, p. 3, line 10. With respect to their use in cosmetics, the specification discloses that said compositions are "particularly stable . . . [and]

homogeneous, making possible a uniform and homogeneous make-up . . . [which] can be applied and spread easily . . . without leaving a feeling of greasiness." Id., p. 3, lines 17-19 and p. 4, lines 5-6.

According to the specification (p. 4, lines 11-17), "[t]he term 'anhydrous composition' is understood to mean a composition comprising less than 5% by weight of water with respect to the total weight of the composition, preferably from 1% to 2% of water, more preferably less than 1% of water. Most preferably still, the composition does not comprise water at all. The compositions of the invention are preferably devoid of polyvalent alcohols, that is to say of alcohols comprising at least two OH groups, such as propylene glycol, butylene glycol, glycerol or sorbitol."

I. Claims 1-4, 7-16, 18-37, 40-49, 51-69, 76 and 77

The examiner argues that Nojima discloses anhydrous cosmetic compositions which contain "from 0.1% to 50% of polyoxyalkylene modified organopolysiloxanes (including those of the instant invention), from 1 to 90% of an oil such as solid, semi-solid or liquid oil (e.g. silicone oil, waxes, hydrogenated jojoba oil, lanolin, liquid paraffin, etc), from 0.1 to 95% of pigments (e.g. talc, mica, silica, polyethylene power [sic, powder], titanium oxide, iron oxide, zinc oxide, iron oxide-coated mica, silicone-treated pigments, etc.) and other cosmetically acceptable substances." Answer, pp. 3-4. The examiner further argues that the cosmetic compositions disclosed by Nojima "are free from polyhydric alcohols." Id., p. 4. The

examiner acknowledges that "Nojima does not explicitly teach the claimed combination of at least one silicone oil, at least one pigment and at least one oxyalkylenated silicone substituted at the α and ω positions"; however, he concludes that because Nojima teaches each of the elements of the claimed invention,

> [i]t is within the skill of an ordinary practitioner to select silicone oils among other oils disclosed by Nojima and the organopolysiloxanes substituted at the α and ω positions among four other organopolysiloxanes disclosed by Nojima by routine experimentation. One having ordinary skill in the art would have been motivated to do this to obtain the desired cosmetic properties of the compositions [Answer, p. 4].

The appellants disagree, arguing that there is no suggestion to pick a oxyalkylenated silicone substituted at the α and ω positions from the four (4) types of oxyalkylenated silicones disclosed in the patent (Brief, pp. 14-16) and to combine said oxyalkylenated silicone (substituted at the α and ω positions) with at least one silicone oil (pp. 16-18) when the patent discloses twenty (20) examples of solid oils, semisolid oils and liquid oils. According to the appellants, Nojima discloses eighty (80) different oil "options from which to choose, only two of which may read on the presently claimed invention," without providing any reasons for choosing the silicone oil required by the present invention. Brief, p. 18.

It is well established that the examiner has the initial burden under § 103 to establish a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). To that end, it is the examiner's responsibility to show that some objective teaching or suggestion in

the applied prior art, or knowledge generally available [in the art] would have led one of ordinary skill in the art to combine the references to arrive at the claimed invention. Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996).

Here, we find that the claims are directed to a subgenus of compounds, which the examiner alleges is embraced by the genus of compounds taught by Nojima. However, the fact that the claimed compound may be encompassed by the prior art genus does not, by itself, render said compound obvious. In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992). According to the examiner, one must first select an oxyalkylenated silicone substituted at the α and ω positions from the polyoxyalkylene-modified organopolysiloxanes set forth in column 2 of Nojima and then select a silicone oil from the possible solid, semi-solid and liquid oils set forth in column 3 (lines 38-63), to produce one of the claimed compositions. Thus, by picking and choosing, amongst the genus of compounds disclosed by Nojima, one of ordinary skill in the art might eventually arrive at a compound within the scope of the claims. We do not agree with this reasoning. In view of the large number of variables taught by the applied prior art, we find that it is necessary for Nojima to provide some suggestion or motivation to make the claimed species or subgenus in order to render the claimed invention obvious. In re Baird, 16 F.3d at 382. No such teachings have been pointed out by the examiner. Accordingly, given the myriad of possible compounds taught by Nojima, and the lack of any suggestion to select the

oxyalkylenated silicone and silicone oil necessary to make the compounds described in the claims, we cannot sustain this rejection.

Accordingly, Rejection I is reversed.

II. Claims 17 and 50

Since the affirmance of the rejection of claims 17 and 50 is contingent upon our finding that the subject matter of claims 1-4, 7-16, 18-37, 40-49, 51-69, 76 and 77 would have been obvious to one of ordinary skill in the art in view of the teachings of Nojima, which we did not, it reasonably follows that we reverse this rejection as well.

REVERSED

Joan Ellis Administrative Patent Judge	)
Donald E. Adams Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Eric Grimes Administrative Patent Judge	)

JE/eld

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